REMARKS

Status of the Claims.

Claims 1-4, 6-10, 20-29, 31 and 32 are pending with entry of this amendment, claims 5, 11-19, and 30 being cancelled and new claim 32 being added herein.

Supplemental IDS.

A supplemental Information Disclosure Statement (IDS) is provided herewith. The references cited on accompanying form PTO-1449 are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited information be expressly considered during the prosecution nfo this application and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom..

No inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

35 U.S.C. §112, First Paragraph.

The rejection of claims 1-4, 6-10, 20-29, and 31 under 35 U.S.C. §112, first paragraph was maintained. The Examiner alleged that the specification is not enabling for a method of increasing the efficacy of a gastric H+/K+-ATPase inhibitor (PPI) in a human in need of a PPI by administering an effective amount (e.g., 0.1-10 mg/kg/hr) of a pentagastrin, a gastrin, or a gastrin analogue in conjunction with the PPI" . . . "because the specification discloses cursory conclusions without data supporting the findings . . . ". Applicants traverse.

The Examiner does not allege that practicing the claimed method (administering a PPI in conjunction with pentagastrin, gastrin, or a gastrin analogue) would itself required undue experimentation, but rather ***the Examiner asserts that Applicants have not provided sufficient data to support the claimed method.***

Applicants first note that the Examiner's allegation that the claims are not enabled because the specification fails to provide sufficient supporting data, is improper. Applicants have provided **objective evidence** that pentagastrin increases the efficacy of a typical PPI. As explained in

the previous response, Barda *et al.* (2004) *Supplement to Gastroenterology*, 12(4): Suppl. 2, Abstract M1439 states:

> These data indicate that **prestimulation of gastric proton pumps with oral PG [pentagastrin] enhances the inhibitory effect of omeprazole** [a PPI] on acid secretion. This effect is mediated by a local effect of PG. **Co-administraton of PG and omeprazole may be used clinically to potentiate the therapeutic effect of omeprazole**. [emphasis added]

In response, the Examiner alleged the Barda *et al.* reference

1) Does not refer to any of applicant's publications; and

2) It clearly does not follow the "teachings" of instant application.

The Examiner is respectfully reminded that **there is no** requirement that references cited in support of the efficacy of a claimed method refer to any of Applicants' own publications. If the Examiner wishes to maintain this as a basis to discount the accuracy or clear teaching of a published reference, **she invited to provide and/or identify the legal basis for this position**.

With respect to the Examiner's allegation that the cited abstract does not follow the teaching of the instant application, **the Examiner is invited to explain the basis and significance of this allegation.**

The cited reference clearly teaches that prestimulation gastric proton pumps with oral PG (pentagastrin) **enhances the inhibitory effect of omeprazole (a PPI) on acid secretion.** The pending claims are drawn to a method of increasing the efficacy of a gastric H+/K+-ATPase pump inhibitor (PPI) in a human in need of a PPI by administering a PPI in conjunction with pentagastrin, gastrin or a gastrin analogue.

The cited reference thus clearly and unambiguously supports the efficacy of the claimed method. Moreover, it is noted that claim 32 is drawn to the use of **pentagastrin** in conjunction with **omeprazole**, precisely the combination described in the cited reference.

With respect to the use of gastrin, or gastrin analogues instead of pentagastrin, the Examiner has failed to offer any objective evidence that would lead one of skill to conclude that gastrin or gastrin analogues would function differently than pentagastrin in the presently claimed method.

With respect to the use of PPIs other than omeprazole, the Examiner has failed to offer any objective evidence that would lead one of skill to conclude that other PPIs would function differently than omeprazole in the presently claimed method.

With respect to the fact that the abstract pertains to testing in rats, the Examiner is reminded that data from *in vitro* or animal testing is generally sufficient to support therapeutic utility. M.P.E.P. §2107.02(c). More particularly, M.P.E.P. §2107.02(c) states that:

> If reasonably correlated to the particular therapeutic or pharmacological utility, data generated using *in vitro* assays, or from testing an animal model or a combination thereof ***almost invariably*** will be sufficient to establish therapeutic or pharmacological utility for a compound, composition, or process. [emphasis added].

In summary, Applicants have provided objective experimental evidence establishing the efficacy of the presently claimed method. To maintain the rejection under 35 U.S.C. §112, first paragraph, or §101/§112, the burden is on the Examiner to provide objective evidence establishing that Applicants invention does not function as claimed. Without such objective evidence, the Examiner has failed to make here *prima facie* case and the rejection under 35 U.S.C. §112, first paragraph, must be withdrawn.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. **Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor**.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,

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